

#### Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

**Important:** This package insert is designed to provide Instructions For Use of the REALIZE™ Adjustable Gastric Band (REF RLZB22). The Instructions For Use for the REALIZE Injection Port and Applier (REF RLZPT2) are available as a separate insert in the RLZB22 gastric band package. It is not a reference to surgical techniques.

REALIZE is a trademark of Ethicon Endo-Surgery.



Instructions For Use

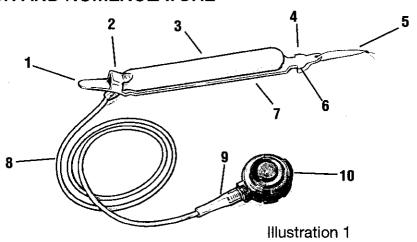
#### **DEVICE DESCRIPTION**

The REALIZE™ Adjustable Gastric Band (referred to as the Band throughout this document) is a laparoscopically implanted medical device manufactured by Obtech Medical. This device is intended for use in the surgical treatment of morbid obesity. The REALIZE Band implant is a silicone assembly that consists of three integral components: the reinforcing band, the balloon and the tubing (See Illustration 1). The REALIZE Band comes in one size, and the fit is customized by increasing or decreasing the amount of fluid in the balloon component by way of the REALIZE Injection Port (referred to as Injection Port throughout this document).

The reinforcing band provides structural support for the balloon and contains the mechanisms for joining the ends of the Band together. The reinforcing band is made from silicone elastomer that contains 10% BaSO<sub>4</sub> which allows the reinforcing band to be visualized by radiography. The balloon is designed to hold anywhere from 0 to 9 ml of saline and provides 360° coverage around the stomach. One end of the tubing is pre-attached to the balloon, and the other end must be connected to the Injection Port during surgery. See REALIZE Injection Port and Applier Instructions for Use (IFU).

The Band is wrapped around the upper stomach to form an artificial stoma. This placement creates a small pouch, or antechamber, in the proximal stomach and a larger pouch in the distal stomach. After the Band is in place, the patient cannot consume large quantities of food, and weight reduction ensues. In general, clinical management goals are 0.5 to 1.0 kg (1 to 2 lbs.) weight loss per week along with the patient's ability to consume a recommended diet without vomiting. Close medical follow-up care is required as long as the Band remains in place.

#### ILLUSTRATION AND NOMENCLATURE



- 1. Tab
- 2. Buckle
- 3. Balloon
- 4. Lock Indicator Diamond (not visible)
- 5. Suture Loop

- 6. Lock-End Flap
- 7. Reinforcing Band
- 8. Tubing
- 9. Locking Connector
- 10. Injection Port (see separate IFU)

#### INDICATIONS FOR USE

The Band is intended for use in weight reduction for morbidly obese patients and is indicated for individuals with a Body Mass Index (BMI) of at least 40 kg/m², or a BMI of at least 35 kg/m² with one or more co-morbid conditions. The Band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.

#### **CONTRAINDICATIONS**

- Inflammatory diseases of the gastrointestinal tract, including severe intractable esophagitis, gastric ulceration or duodenal ulceration, or specific inflammation such as Crohn's disease;
- Severe cardiopulmonary disease or other serious organic disease;
- Upper gastrointestinal bleeding conditions such as esophageal or gastric varices or intestinal telangiectases;
- Portal hypertension;
- Anomalies of the gastrointestinal tract such as atresia or stenosis;
- Cirrhosis of the liver;
- Chronic pancreatitis;
- Less than 18 years of age;
- Localized or systemic infection;
- Patients on chronic, long-term steroid treatment or steroids within 15 days of surgery;
- Unable or unwilling to comply with dietary restrictions required by this procedure;
- Known allergy to materials contained in the Band or its Injection Port;
- Pregnancy: Women who are pregnant. Patients who become pregnant after Band placement may require fluid removal from their Band.

#### WARNINGS

- Laparoscopic or laparotomic placement of the Band is major surgery, and death can occur
- Always confirm secure closure of the Band. Failure to properly secure the Band may result in its subsequent displacement, migration, failure of effectiveness and repeat surgery.
- A hiatal hernia may require repair prior to Band placement. The presence of a hiatal hernia may impair proper band placement and may predispose the patient to Band slippage in some cases.
- The Band should not be sutured to the stomach. Suturing the Band directly to the stomach may result in erosion.
- Gastric banding may not be appropriate in patients with emotional or mental instability.
- Band placement after an intraoperative gastric injury may increase the risk of infection.
- Esophageal distention or dilation has been reported to result from stoma obstruction due
  to over-restriction, due to excessive band inflation. Patients should not expect to lose
  weight as fast as gastric bypass patients, and band inflation should proceed in small
  increments. Deflation of the band is recommended if esophageal dilation, pouch dilation,
  stoma obstruction or evidence of slippage develops.
- Some types of esophageal dysmotility may result in inadequate weight loss or may result in esophageal dilatation when the Band is inflated and may require removal of the Band.

On the basis of each patient's medical history and symptoms, surgeons should determine whether esophageal motility function studies are necessary. If these studies indicated that the patient has esophageal dysmotility, the increased risks associated with Band placement must be considered.

- Patients with Barrett's esophagus may have problems associated with their esophageal
  pathology that could compromise their post-surgical course. Use of the Band in a patient
  with Barrett's esophagus should be based on the individual patient's need and severity of
  the disease.
- Patients should be warned not to attempt to self-adjust the band. Self-adjustment by injecting or removing fluid may result in inappropriate Band tightness, loss of restriction, infection, and other complications.
- Access port infection may be a sign of band erosion into the stomach and should be evaluated as clinically indicated.
- Placing the Band through a trocar smaller than 15 mm may damage the Band.
- Do not use an oil-based lubricant to ease passage of the Band through a trocar. Use of an oil-based lubricant may lead to saline leakage from the balloon and subsequent failure of the device to function as intended. Use a sterile water-based lubricant if needed.
- Remove any gastric tubes from the stomach before beginning dissection close to the stomach. Failure to do so may result in gastric or esophageal perforation, particularly during dissection posterior to the stomach.
- Avoid the retrogastric portion of the lesser sac during dissection, and do not place the Band around the stomach at the level of the lesser sac. Placing the Band below the lesser sac may increase the risk of Band slippage and gastric prolapse.
- Do not inflate the gastric calibration tube in the esophagus. Doing so may result in esophageal perforation, leading to infection and possibly death.
- When placing gastro-gastric imbrication sutures, do not place sutures into any part of the Band. Doing so may cause balloon leakage and make the Band ineffective.
- Never fill the Band with more than 9 ml of saline. Filling with greater than 9 ml of saline may result in stoma obstruction, Band slippage, esophageal dilation, gastric prolapse, or Band erosion. Any of these conditions may require a second surgery. The risk of these adverse events may be reduced by gradually filling the Band over specified time intervals.
- Band erosion is a potentially serious event and can lead to serious complications including death.
- Obstructive symptoms, such as inability to swallow, may develop after a Band adjustment. Counsel patients to contact their physician immediately if obstructive symptoms develop. If a stoma is obstructed, withdraw a sufficient amount of saline from the Band to ensure an adequate stoma.

Additional Warnings may also appear in the INSTRUCTIONS FOR USE section.

#### **PRECAUTIONS**

• The REALIZE Band with Injection Port and Applier is for single use only. Do not use a band, injection port, or needle which appears damaged (cut, torn, etc.) in any way. Do not use one of them if the package has been opened or damaged, or if there is any evidence of tampering. If packaging has been damaged, the product may not be sterile and may cause an infection. Do not attempt to clean, re-sterilize or re-use the REALIZE Band or the REALIZE Injection Port and Applier. The product may be damaged or

distorted if re-sterilized.

- It is important that special care be used when handling the device because contaminants such as lint, fingerprints and talc may lead to a foreign body reaction.
- Placement of the Band is an advanced laparoscopic surgical procedure. Surgeons who plan to perform this procedure must:
  - Have advanced laparoscopic surgical skills and experience, e.g., laparoscopic hernia repair, gastric fundoplications, and suturing.
  - Complete formal training by the manufacturer or one of its appointed preceptors.
  - Have previous experience in the surgical treatment of obesity.
  - Have the commitment and ability to undertake long-term follow-up care of patients undergoing surgical treatment for obesity.
  - Be prepared to complete the procedure by an open technique if required.
- It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant.
- As with other gastroplasty surgeries, particular care must be taken during dissection and during implantation of the device to avoid damage to the gastrointestinal tract. Any damage to the stomach during the procedure may result in erosion of the device or development of infection.
- Avoid damage to any part of the Band. Keep sharp instruments away from the balloon component. Do not grasp the balloon with any instrument. Grasping the balloon may cause leaks and ultimate failure of the Band. If damage is real or suspected, replace the Band immediately. For this reason, another Band should be available at the time of surgery.
- Advise patients to avoid non-steroidal anti-inflammatory drugs (NSAIDS). These drugs may irritate the stomach and may increase the risk of Band erosion into the stomach.
- Patients who become pregnant or severely ill, who require more extensive nutrition, or who require upper gastrointestinal endoscopy may require fluid removal from their Bands.
- Elevated homocysteine levels have been found in patients losing weight after obesity surgery. Supplemental folate and vitamin B12 may be necessary to maintain normal homocysteine levels. Elevated homocysteine levels may increase cardiovascular risk. In addition, the developing fetus of pregnant women with elevated homocysteine levels may be at risk for neural tube defects.
- Insufficient weight loss may be caused by pouch enlargement or more infrequently Band erosion, in which case further inflation of the Band would not be appropriate.
- Although there have been no reports of autoimmune disease with the use of the Band, autoimmune diseases, connective tissue disorders (i.e., systemic lupus erythematosus, scleroderma) have been reported following long-term implantation of other silicone devices. There is currently no conclusive clinical evidence to substantiate a relationship between connective-tissue disorders and silicone implants. However, the surgeon should be aware that if autoimmune symptoms develop following implantation, definitive treatment and/or Band removal may be indicated.
- Patients who exhibit preexisting autoimmune symptoms should be carefully evaluated prior to implantation of the Band and may not be appropriate candidates.
- When laparoscopic instruments and accessories from different manufacturers are employed together in a gastric banding procedure, verify instrument compatibility prior to surgery. This is because minimally invasive instruments from different manufacturers may vary in dimensions.

- Place the Injection Port in a stable position away from areas that may be affected by significant weight loss, physical activity, or subsequent surgery. Failure to do so may result in the inability to perform percutaneous band adjustments, or may require repositioning of the Injection Port.
- During placement of the Injection Port, keep sharp instruments away from the gastric band tubing component. When grasping the tubing, avoid puncture as this will cause leakage of the filling solution from the Band.
- Do not add saline to the balloon for approximately four weeks after placing the Band. Early filling may result in Band slippage, gastric prolapse, and esophageal dilation.
- Use only a Huber (non-coring) needle when performing band adjustments. Any other type of needle may damage the Injection Port septum. Band adjustments are described in the specific adjustable gastric band Instructions For Use.
- Close, periodic medical follow-up care is necessary as long as the Band remains implanted. Patients should be assessed regularly for clinical evidence of esophagitis, esophageal dilation, gastro esophageal reflux (GERD), and malnutrition. Fiberoptic endoscopy and/or radiographic contrast studies should be performed when necessary to establish a diagnosis and to monitor therapy, as indicated.

Additional Precautions may also appear in the INSTRUCTIONS FOR USE section.

#### **ADVERSE EVENTS**

#### Adverse Events Observed in the US Clinical Study

The following adverse events (AEs) were reported during a prospective, single-arm, multicenter clinical study of the first generation Band (including the first generation Injection Port) in the treatment of morbid obesity in 276 subjects over a period of three years. Adverse events are reported as n = number of subjects.

All adverse events in the U.S. clinical study that occurred with a frequency > 5% are listed in the following table. Other peri-operative and post-operative AEs were reported in < 5% of subjects.

### Common Adverse Events (> 5%) in the U.S. Trial

Gastrointestinal Disorders   (N=276)	System Organ Class	# of Subjects
Vomiting         124 (44.9%)           Nausea         88 (31.9%)           Constipation         69 (25.0%)           Gastroesophageal Reflux Disease         53 (19.2%)           Abdominal Pain         29 (10.5%)           Abdominal Pain Upper         28 (10.1%)           Flatulence         28 (10.1%)           Diarrhea         26 (9.4%)           Dysphagia         26 (9.4%)           Dyspepsia         23 (8.3%)           Post Procedural Nausea         14 (5.1%)           General Disorders And Administration Site Conditions         Fatigue           Port Site Pain         18 (6.5%)           Migration of Implant²         17 (6.2%)           Catheter Related Complications         15 (5.4%)           Chest Pain         14 (5.1%)           Infections And Infestations         15 (5.4%)           Nasopharyngitis         31 (11.2%)           Influenza         26 (9.4%)           Sinusitis         23 (8.3%)           Upper Respiratory Tract Infection         21 (7.6%)           Urinary Tract Infection         21 (7.6%)           Urinary Tract Infection         21 (7.6%)           Injury, Poisoning And Procedural Complications         66 (23.9%)           Musculoskeletal An	(MedDRA) Preferred Term¹	(N=276)
Nausea         88 (31.9%)           Constipation         69 (25.0%)           Gastroesophageal Reflux Disease         53 (19.2%)           Abdominal Pain         29 (10.5%)           Abdominal Pain Upper         28 (10.1%)           Flatulence         28 (10.1%)           Diarrhea         26 (9.4%)           Dysphagia         26 (9.4%)           Dyspepsia         23 (8.3%)           Post Procedural Nausea         14 (5.1%)           General Disorders And Administration Site Conditions           Fatigue         29 (10.5%)           Port Site Pain         18 (6.5%)           Migration of Implant²         17 (6.2%)           Catheter Related Complications         15 (5.4%)           Chest Pain         14 (5.1%)           Infections And Infestations         14 (5.1%)           Nasopharyngitis         31 (11.2%)           Influenza         26 (9.4%)           Sinusitis         23 (8.3%)           Upper Respiratory Tract Infection         21 (7.6%)           Urinary Tract Infection         21 (7.6%)           Urinary Tract Infection         21 (7.6%)           Injury, Poisoning And Procedural Complications           Post Procedural Pain         66 (23.9%)		1404 (44.00()
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Upper Respiratory Tract Infection 21 (7.6%)  Urinary Tract Infection 21 (7.6%)  Injury, Poisoning And Procedural Complications  Post Procedural Pain 66 (23.9%)  Musculoskeletal And Connective Tissue Disorders  Back Pain 41 (14.9%)  Arthralgia 27 (9.8%)  Nervous System Disorders  Headache 38 (13.8%)  Psychiatric Disorders  Depression 28 (10.1%)	Influenza	26 (9.4%)
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Psychiatric Disorders  Depression 28 (10.1%)		38 (13.8%)
Depression 28 (10.1%)	Psychiatric Disorders	· · · · · · · · · · · · · · · · · · ·
		28 (10.1%)

#### Common Adverse Events (> 5%) in the U.S. Trial, cont.

Skin and Subcutaneous Tissue Disorders	
Alopecia	24 (8.7%)
Vascular Disorders	
Hypertension	15 (5.4%)
Post-operative Hypertension	15 (5.4%)

<sup>&</sup>lt;sup>1</sup> MedDRA is the acronym for Medical Dictionary for Regulatory Activities which is a pragmatic, medically valid terminology with an emphasis on ease of use for data entry, retrieval, analysis, and display.

A total of 73.2% (202) of the study subjects experienced one or more AEs peri-operatively (30 days following surgery). Postoperative AEs (> 30 days following surgery) were reported in 93.8% (259) of study subjects. Many adverse events were mild and required no intervention. Some serious and severe adverse events required band adjustment or re-operation to revise, replace or remove the necessary components).

#### Device-Related Adverse Events Associated with Gastric Band

The following AEs associated with gastric banding were reported during the course of the US study:

#### **Device-related Adverse Events (US Study)**

Adverse Event	# of Events	# (%) of Subjects	Peri- Operative ≤ 30 Days following surgery N=Subjects	Post-operative > 30 Days following surgery N=Subjects
Port site pain	21	18 ( 6.5%)	4	15
Band slippage / Pouch dilatation	23	17 ( 6.2%)	0	17
Catheter-related complications	17	15 ( 5.4%)	0	15
Stoma obstruction	12	12 ( 4.3%)	1	11
Esophageal dilatation/ dysmotility	10	10 ( 3.7%)	0	10
Port displacement	9	7 ( 2.5%)	0	7
Band erosion	1	1 ( 0.4%)	0	1
Band leak	1	1 ( 0.4%)	0	1

Note: Subjects may have reported an event in both the peri- and post-operative study periods.

<sup>&</sup>lt;sup>2</sup> "Migration of Implant" refers to band slippage, port displacement, and band erosion and should not be considered the same as "Device Migration," which is a term frequently used in the clinical literature to refer to the "erosion" of the band into the GI tract.

Eighteen (6.5%) subjects in the US study reported injection port site pain. Most were reported as mild; one case was reported as severe. Four (1.4%) subjects reported injection port site pain during the peri-operative period and 15 (5.4%) in the post-operative period. One subject reported this event at some point during both study periods. Port displacement was reported in 7 (2.5%) subjects. All events related to port displacement required surgical revision of the port.

In the US study, radiographic changes in the relative position of the band from the original implantation position were reported as "band slippage". Pouch enlargement without change in the baseline band position was reported as "pouch dilatation." During the US study, routine limited upper GI series were required in association with band adjustments; therefore, band slippage and pouch dilatation were primarily radiological findings reported by the study sites. Eleven events of band slippage were reported in nine (3.3%) subjects; twelve events of pouch dilatation were reported in 10 (3.6%) subjects. In two subjects, both band slippage and pouch dilatation was reported. Therefore, 17 (6.2%) subjects reported band slippage/pouch dilatation. All subjects with band slippage were symptomatic and events were resolved with band adjustment or surgical revision. Eight of ten subjects with pouch dilatation reported associated symptoms. Most events were resolved with band adjustment or surgical revision. Band erosion into the gastric lumen was reported in one subject (0.4%). The gastric defect secondary to the erosion was closed without complications.

Fifteen (5.4%) subjects reported complications related to the catheter, all reported in the post-operative period. These events involve the disconnection of the injection port from the catheter that connects it to the adjustable band as well as those events involving a kink in the catheter that impeded the withdrawal of saline from the band. Port disconnections were reported for twelve (4.3%) subjects. In the study, all port disconnections required surgical reconnection. In two subjects, the investigator also replaced the port. Investigators reported a catheter kink for 3 (1.1%) subjects based on the inability to withdraw saline from the band (i.e., to resolve band overfill) during a band adjustment. All events related to catheter kinking required surgical revision of the port.

Stoma obstruction (gastric outlet obstruction) was reported in 12 (4.3%) of subjects. Signs and symptoms associated with stoma obstruction included nausea/vomiting, heartburn/reflux, abdominal pain, dehydration, coughing, band slippage. Most events resolved after removal of saline of the band. In one subject, the event resolved with no intervention and one other (reported as food impaction) with nutritional counseling.

Esophageal dilatation was reported in 9 (3.3%) subjects. Seven of the nine cases resolved after band deflation. The other two cases, reported 3 years post-operatively, were also treated with band deflation and were still ongoing at time of study completion. No cases of esophageal dilatation were reported as serious, required surgical revision, or required device explantation. Esophageal dysmotility was reported in one (0.4%) subject.

Band leakage was reported in one subject (0.4%). During routine band adjustment in the US study, the investigator noted less fluid in the band than previously observed. The leak was confirmed radiographically, and the band was subsequently replaced laparoscopically without further incident.

#### Serious Adverse Events Observed in the US Study that may be related to the Gastric Band

One hundred fifteen (115) serious adverse events (SAEs) were reported during the US study in 78 (28.3%) subjects. Of these events, only 13 (11.3%) were considered unanticipated and related to the gastric band; 46 (40%) were considered unanticipated but not related to the gastric band; and the remaining 56 (48.7%) were considered anticipated. There was one death in the study. Causality is probably related to port replacement surgery. The patient was seen approximately 23 months post-implantation with an incarcerated trocar site hernia in close proximity to the port site. The patient underwent an uneventful hernia repair. Following the hernia repair the patient developed a chronically draining wound at the trocar site which did not respond to standard antibiotic therapy. A decision was made to relocate the port, replacing the port and tubing 17 months after the hernia repair surgery. Twelve hours following this surgery, the patient became acutely ill and died of multi-organ system failure. The perioperative clinical course and subsequent post mortem identified a gastric perforation causing intra-abdominal sepsis as a major contributing factor to the patient's death. This may have been an acute process, as suggested by the post mortem finding, however, an unrecognized band erosion resulting in a chronically discharging wound site may have been a contributing factor. These events would not have occurred de-novo in the absence of gastric band implantation.

No other SAEs were reported as life-threatening, associated with disability, or resulted in a congenital anomaly. A description of the events as well as the number of incidents and subjects are reported in the following table.

### Serious Adverse Events Considered Related to the Gastric Band (U.S. Study)

System Organ Class and/or MedDRA Preferred Term	# of Events	# of Subjects
Gastrointestinal Disorders		
Gastric Dilatation	3	3 ( 1.1%)
Gastric Outlet Obstruction	3	3 ( 1.1%)
Abdominal Hernia	. 1	1 ( 0.4%)
Constipation	1	1 ( 0.4%)
Gastrointestinal Oedema	1	1 ( 0.4%)
Gastroesophageal Reflux Disease (GERD)	1	1 ( 0.4%)
Oesophageal Spasm	1	1 ( 0.4%)
Oesophagitis	1	1 ( 0.4%)
Procedural Complications		
Gastrointestinal Injury	2	2 ( 0.7%)
Device Failure	1	1 ( 0.4%)
Surgical Procedure Repeated	1	1 ( 0.4%)
Catheter Related Complications	15	14 ( 5.1%)
Band Slippage	9	9 ( 3.3%)
Injection Port Displacement	7	7 ( 2.5%)
Cholelithiasis	5	5 ( 1.8%)
Cholecystitis	4	4 ( 1.4%)
Chest Pain	3	3 ( 1.1%)
Atelectasis	1	1 ( 0.4%)
Band Erosion	1	1 ( 0.4%)
Biliary Colic	1	1 ( 0.4%)
Cardiomegaly	1	1 (0.4%)
Cholecystitis Acute	1	1 ( 0.4%)
Dehydration	1	1 (0.4%)
Injection Site Infection*	1	1 ( 0.4%)
Pulmonary Microemboli	1	1 ( 0.4%)
Renal Tubular Necrosis	1	1 ( 0.4%)
Death	1	1 ( 0.4%)

<sup>\*</sup> The term "Injection Site" in all MedDRA terms selected in this study refer to the "Port Site."

#### Re-operations

Forty-three subjects (15.2%) required re-operations, including: 2 band replacements, 10 band revisions, 4 band explantations, 5 port replacements, and 22 port revisions. The number of subjects and reasons for the re-operations are listed in the table below

#### Re-Operations involving the Gastric Band (US Study)

	Su	irgery (N = 40	3 subjects)		
Reason	Band Re- placement	Band Revision	Band Explant	Port Re- placement	Port Revision <sup>a</sup>
Band Slippage	1	6			
Tube kinking		<u></u>			3
Pouch dilation <sup>d</sup>		3	· · · · · · · · · · · · · · · · · · ·		
Gastric outlet obstruction		1			
Band leak	1				
GERD			1		
Erosion			1		
Port disconnection		· · ·		2	10
Port infection				2	
Port site pain/ wound drainage				1	
Port displacement					7
Epigastric pain due to over-inflation					1
Ventral hernia with incarcerated bowel above port <sup>b</sup>					1
Perceived insufficient weight loss °			2		

<sup>&</sup>lt;sup>a</sup> Port revision includes reconnection and/or repositioning of the port.

<sup>&</sup>lt;sup>b</sup> Event required surgical repair of ventral hernia. Hernia was near the injection port site; therefore, investigator moved the injection port to new location.

<sup>&</sup>lt;sup>c</sup> Two subjects (0.7%) withdrew informed consent and had their Bands explanted due to perceived insufficient weight loss within the third year of the study follow-up.

<sup>&</sup>lt;sup>d</sup>One pouch dilation occurred after the study completion.

#### Adverse Events Reported in the Literature

The following adverse events have been reported in the literature as having resulted from laparoscopic placement of adjustable gastric bands and are considered to be potential complications for the Band.

- Complications associated with any laparoscopic procedure including bleeding, thrombosis, carbon dioxide gas embolism, pain, pneumonia, wound infection, incisional hernia, conversion to open surgery, stroke, and death.
- Organ damage associated with any laparoscopic procedure including perforation of the stomach, esophagus, spleen, liver, major blood vessels and lungs.
- Nausea and vomiting, particularly in the first few days after surgery and when the patient does not adhere to the prescribed diet plan and appropriate eating behaviors. Nausea and vomiting may also be symptoms of stoma obstruction, gastric prolapse, or Band slippage. Frequent, severe vomiting can result in pouch dilation, gastric prolapse or esophageal dilation. Fluid removal from the Band is often required to resolve these complications.
- Regurgitation can occur for many reasons and is expected as a patient learns to make appropriate food choices and becomes accustomed to new eating behaviors. Patients may regurgitate if they make poor food choices, do not chew well, or eat too fast.
- Gastroesophageal reflux, dysphagia, constipation, ulceration, gastroenteritis, gas bloat, esophageal dysmotility, infection, hernia, general intolerance and weight re-gain.
- Fluid leakage from the balloon or tubing due to improper handling during surgery, the use
  of an incorrect filling solution, tubing puncture during Band adjustments, or disconnection
  of the tubing from the Injection Port. The manufacturer cannot assume any liability
  or responsibility for loss of the filling fluid resulting from improper handling and use,
  physiological reaction to the material, general deterioration of the balloon over time, or
  similar reasons.
- <u>Band slippage</u> resulting in nausea, vomiting, stoma obstruction, abdominal pain and gastric prolapse. Band slippage can be detected by contrast radiography. Depending on severity, this may require Band deflation, or a second operation to reposition or remove the Band.
- <u>Stoma obstruction</u> due to over-filling the Band, edema, Band slippage, pouch torsion, gastric invagination into the stoma, or patient non-compliance (eating improper foods, not chewing food thoroughly).
- Esophageal dilation due to early Band filling during the post-operative period, overfilling
  the Band, Band misplacement or patient non-compliance (over-eating). The risk of
  esophageal dilation may be reduced by incremental Band adjustments over time (See
  BAND ADJUSTMENT GUIDELINES). Esophageal dilation can be detected by contrast
  radiography. Depending on severity, it may require fluid removal from the Band or a
  second operation to reposition or remove the Band.
- <u>Infection at the area</u> of the Band, the Injection Port, or both devices. Depending on severity, it may require device removal.
- Band erosion into the stomach due to extensive dissection, use of electrocautery, gastric
  irritating medications, port infections and revision surgery. Symptoms of Band erosion
  may include reduced weight loss, weight gain, Injection Port infection, or abdominal
  pain. Erosion can be detected by endoscopy. Depending on severity, it may require
  Band deflation or a second operation to remove the Band and allow the stomach to
  heal. Eroded Bands have been removed using gastroscopy, depending on the degree of

erosion. Consultation with an experienced gastric banding surgeon is strongly advised in these cases.

The following adverse events have been reported to result from rapid or significant weight loss regardless of the method used to achieve weight loss.

- <u>Malnutrition</u>, <u>anemia and related complications</u>. Fluid removal from the Band may be required.
- Cholelithiasis, which may require a cholecystectomy.

#### **CLINICAL STUDY**

Clinical data from a prospective, single-arm, multi-center clinical study in the United States were collected to evaluate the safety and effectiveness of the first generation Band in the treatment of morbid obesity. The subject's baseline weight served as the control. The primary effectiveness parameter measured percent excess weight loss (%EWL) at three years post-surgery. Percent EWL is defined as the difference in the baseline and post-surgery weight divided by the difference in baseline weight and ideal body weight, multiplied by 100. Ideal Body Weight was determined using the upper limit value of the medium frame range from the 1983 Metropolitan Tables for Life Insurance, multiplied by 100. The primary safety parameter measured the rate of device-related adverse events and device malfunctions throughout the three-year post-operative period.

To quality for enrollment in the study, subjects met all the inclusion criteria and none of the exclusion criteria listed below.

#### Study Inclusion Criteria

- Able to comprehend, follow and give signed informed consent
- 18 to 60 years of age (inclusive)
- Five (5) year history of morbid obesity
- BMI ≥ 40 and ≤ 55 kg/m² or BMI ≥ 35 and < 40 kg/m², with one or more co-morbidities related to obesity¹
- 100 lbs. overweight, or 1.5 times ideal weight
- Documented failure of conservative, non-surgical means of weight reduction within one year prior to study
- Willing to commit to significant lifestyle changes that include diet, eating and exercise habits for the duration of the study
- Able to commit to three-year follow-up, including Band adjustment visits
- Living within the contiguous United States and within a 100 mile radius of the study center
- Absence of significant psychopathology that could limit subject's ability to comply with study protocol

<sup>&</sup>lt;sup>1</sup> These were conditions for which the subject was being treated, and which were generally expected to be improved, reversed, or resolved by weight loss. These included: type 2 diabetes, hyperlipidemia, obstructive sleep apnea, hypertension, metabolic syndrome, or osteoarthritis of the hip or knee.

- Willing to refrain from reconstructive surgery that would affect body weight (abdominal lipoplasty or liposuction, mammoplasty, removal of excess skin) for three years following device placement
- Meets accepted health criteria for major surgery

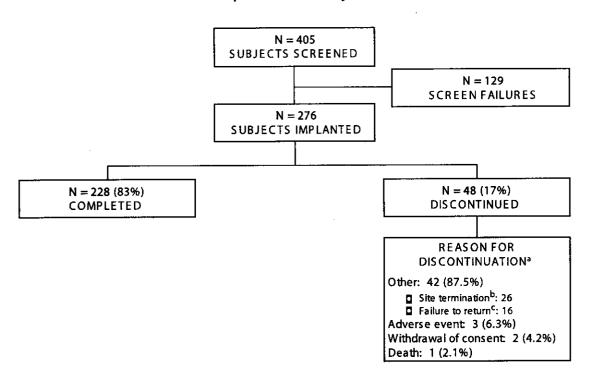
#### **Study Exclusion Criteria**

- Women of childbearing potential who are not practicing an effective method of birth control or who are pregnant or lactating
- Previous malabsorptive or restrictive procedures performed for treatment of obesity
- Documented history of drug and/or alcohol abuse within two years prior to study
- History of impaired mental status by DSM4 criteria
- Presence of any of the following medical conditions:
  - Inflammatory diseases of the gastrointestinal tract, including severe intractable esophagitis, gastric ulceration, duodenal ulceration, or specific inflammation such as Crohn's disease active within the past 10 years
  - Anomalies of the GI tract, including atresias or stenosis
  - Severe cardiopulmonary disease or other serious organic disease that makes the subject a high-risk surgical candidate
  - Uncontrolled hypertension
  - Portal hypertension
  - Uncontrolled diabetes mellitus
  - Upper gastrointestinal bleeding conditions, e.g., gastric or esophageal varices
  - Cirrhosis
  - Intestinal telangictasia
  - Esophageal or gastric disorders including severe preoperative reflux, dysmotility or Barrett's Esophagus
  - Hiatal hernia
  - Prior surgery of the foregut including hiatal hernia repair or prior gastric surgery
  - Chronic pancreatitis
  - Compromised immune system
  - Conditions that, in the opinion of the investigator, may jeopardize the subject's well-being and/or soundness of the clinical study
- History or presence of pre-existing autoimmune connective tissue disease, i.e., systemic lupus erythematosus or scleroderma
- Terminal illness with life expectancy ≤ 5 years
- Use of prescription or over-the-counter weight reduction medications or supplements within one month of study-screening visit and for the duration of the study
- Acute or chronic infection (localized or systemic)
- Known or suspected allergy to silicone or other materials contained in the Band
- History of intolerance to implanted devices
- Not ambulatory
- Participant in another clinical trial within 8 weeks of screening visit and for the duration of the study

The study initially consisted of 276 subjects at 12 sites. However, one site was affected by Hurricane Katrina, and 26 of 27 subjects from the site were terminated from the study. The Primary (Intent-To-Treat or ITT) study population consisted of 276 subjects implanted with the

device. Secondary study populations included the Evaluable study population, which consisted of 228 subjects that completed the three-year study, and the Per Protocol study population which consisted of 164 subjects that completed the three-year study with no major protocol violations. Post-operative follow-up visits were scheduled at days 1 - 6, 7 - 10 days, 4-6 weeks and at 2, 4, 6, 8, 10, 12, 15, 18, 21, 24, 28, 32 and 36 months.

#### **Disposition of Subjects**



<sup>&</sup>lt;sup>a</sup> Mutually exclusive and exhaustive categories. Percentages are computed based on total number of discontinued subjects as the denominator.

<sup>&</sup>lt;sup>b</sup> Site #269 was terminated after Hurricane Katrina.

<sup>°</sup>Subjects were able to be located and contacted, but unwilling to return for their final visit; subjects did not formally revoke consent to participate in the study.

Subject demographics and other baseline characteristics are identified in the following table.

#### Demographics for 276 Subjects

	Number (Percent)
Gender	
• Female	216 (78.3%)
Male	60 (21.7%)
Race	,
Caucasian, non-Hispanic	169 (61.2%)
Hispanic	67 (24.3%)
Black, non-Hispanic	33 (12%)
Asian/Pacific Islander	4 (1.4%)
Other	3 (1.1%)
Age	
Mean	38.6 years
Range	18 to 61 years
Significant co-morbidities	
Hypertension	118 (42.8%)
Type If diabetes	47 (17.8%)
Sleep apnea syndrome	74 (26.8%)
Hypercholesterolemia	52 (18.8%)
Hyperlipidemia	24 (8.7%)
Band placed laparoscopically	275 (99.6%)
BMI	
• BMI = 35 and <40 kg/m²	42 (15.2%)
• BMI > 40 kg/m²	234 (84.8%)

#### **Effectiveness**

The <u>primary</u> effectiveness endpoint of the clinical study was %EWL at three years post-surgery. Percent EWL was also calculated at follow-up visits. <u>Secondary</u> endpoints included absolute weight, excess weight, and BMI (kg/m²) at follow-up visits. The following table presents data for primary and secondary assessments at three years post surgery. Subsequent tables present data for these assessments at the follow-up visits.

### Effectiveness at Three Years (ITT n = 276 and Evaluable n = 228 Populations)

Assessment	Pre-operative Data (n=276)	Three years post-operative Data a		
%EWL				
• Mean, SD		42.8% ± 25.4 (n=228)		
	NA	41.1% ± 25.1 (n=276)		
Range		-25.6 to 129.3% (n=228)		
		-26.5 to 129.3% (n=276)		
Absolute Weight				
• Mean, SD	276.5 lbs. ± 40.8	222.2 lbs. ± 45.8 (n=228)		
		225.2 lbs. ± 47.8 (n=276)		
Range	193.6 to 415.4 lbs.	114.6 to 336.8 lbs. (n=228)		
		114.6 to 411.2 lbs. (n=276		
Excess Weight				
Mean, SD	130.0 lbs. ± 33.1	75.7 lbs. ± 39.8 (n=228)		
		78.7 lbs. ± 41.3 (n=276)		
Range	61.6 to 233.8 lbs.	-26.4 to 186.8 lbs. (n=228)		
		-26.4 to 241.2 lbs. (n=276)		
ВМІ				
• Mean, SD	44.5 kg/m <sup>2</sup> ± 4.7	35.7 kg/m <sup>2</sup> ± 6.2 (n=228)		
		36.2 kg/m <sup>2</sup> ± 6.3 (n=276)		
Range	35.0 to 58.1 kg/m²	19.7 to 53.5 kg/m² (n=228)		
		19.7 to 55.8 kg/m² (n=276)		

<sup>&</sup>lt;sup>a</sup> Missing values for the ITT population were imputed using Last Observation Carried Forward (LOCF).

The study found differences in the %EWL based on gender. Examination of the gender group, based on subjects who completed the study, indicated that the mean  $\pm$  SD %EWL for males was 35.8  $\pm$  18.2 (range: -5.8 to 89.0) compared to 44.7  $\pm$  26.7 (range: -25.6 to 129.3) for females. 38 males and 126 females completed the study. The male and female groups achieved the %EWL target of 32.6% or more at three years.

Mean %EWL throughout the three-year post-operative period is provided in the following table. There was a statistically significant improvement in %EWL from baseline compared to three years.

### Mean Percent EWL Throughout Post-Operative Period (ITT Population)

Follow-up Visit	Number of Subjects	Mean %EWL
4-6 Weeks	265	15.3
2 Months	266	19.8
4 Months	255	25.0
6 Months	260	28.9
8 Months	258	33.1
10 Months	242	35.9
12 Months	269	38.0
15 Months	248	40.7
18 Months	238	43.1
21 Months	216	43.0
24 Months	225	44.7
28 Months	201	45.7
32 Months	199	44.1
36 Months	228	42.8
36 Months <sup>a</sup>	276	41.1

<sup>&</sup>lt;sup>a</sup> Missing values for the ITT population were imputed using Last Observation Carried Forward (LOCF).

### Secondary Endpoint: Changes in Absolute Weight and Excess Weight.

Mean values for these parameters throughout the three-year post-operative period are provided in the following table. There was a statistically significant reduction in absolute weight and excess weight from baseline compared to three years.

# Absolute Weight and Excess Weight (Mean) Throughout Post-Operative Period (ITT Population)

Visit	Number of Subjects	Absolute Weight, lbs.	Excess Weight, lbs.
Baseline	276	276.5	130.0
6 Weeks	265	256.7	110.7
2 Months	266	251.3	104.9
4 Months	255	244.4	98.0
6 Months	260	239.6	93.4
8 Months	258	235.8	89.1
10 Months	242	230.1	84.1
12 Months	269	228.4	82.0
15 Months	248	225.8	78.9
18 Months	238	220.1	74.2
21 Months	216	221.1	75.1
24 Months	225	220.0	73.4
28 Months	201	217.4	71.2
32 Months	199	219.3	73.4
36 Months	228	222.2	75.7
36 Months <sup>a</sup>	276	225.2	78.7

<sup>&</sup>lt;sup>a</sup> Missing values for the ITT population were imputed using Last Observation Carried Forward (LOCF).

### Secondary Endpoint: Body Mass Index.

Mean BMI values for the study period are provided in the following table. There was a statistically significant improvement in BMI from baseline compared to three years.

Mean BMI Throughout Post-Operative Period (ITT Population)

Follow-up Visit	Number of Subjects	Mean BMI (kg/m²)
Baseline	276	44.5
4-6 Weeks	265	41.4
2 Months	266	40.4
4 Months	255	39.3
6 Months	260	38.6
8 Months	258	37.8
10 Months	242	37.1
12 Months	269	36.8
15 Months	248	36.2
18 Months	238	35.6
21 Months	216	35.8
24 Months	225	35.4
28 Months	201	35.1
32 Months	199	35.4
36 Months	228	35.7
36 Months <sup>a</sup>	276	36.2

<sup>&</sup>lt;sup>a</sup> Missing values for the ITT population were imputed using Last Observation Carried Forward (LOCF).

#### **Excess Weight at 3 years**

	ITT (Intent to Treat <sup>a</sup> ) # (%) of subjects	Evaluable <sup>b</sup> # (%) of subjects
Gained >5% EWL	6 (2.2%)	5 (2.2%)
No Change (-5% to 5%) EWL	8 (2.9%)	6 (2.6%)
EWL between 5% and 25%	56 (20.3%)	41 (18.0%)
Lost at Least 25% EWL	206 (74.6%)	176 (77.2%)
Lost at Least 33 % EWL	166 (60.1%)	143 (62.7%)
Lost at Least 50% EWL	91 (33.0%)	80 (35.1%)
Lost at Least 75% EWL	26 (9.4%)	24 (10.5%)

<sup>&</sup>lt;sup>a</sup> Missing values for the ITT population were imputed using Last Observation Carried Forward (LOCF).

<sup>&</sup>lt;sup>b</sup> Evaluable indicates number of subjects who completed 36 months of follow-up.

#### Secondary Endpoint: Quality of Life.

The SF-36 Questionnaire and Beck Depression Index II were used to measure quality of life. In general, there was an improvement in all the SF-36 component and domain scores compared to baseline for all post-surgery visits, with the exception of the mental health component and role emotional domain score. There were statistically significant (p<0.001) improvements in subject's physical component and domain scores at 36 months. These improvements were maintained throughout the three-year study. 93.8% of subjects continued to have minimal depression starting before surgery and continuing through the three-year follow up visit.

#### Secondary Endpoints: Changes in Co-Morbidities

#### Glycosylated hemoglobin (HbA1c)

The study population experienced a statistically significant (p<0.001) reduction in HbA1c at three years. Over time, there was a greater reduction in glycosylated hemoglobin for subjects with a history of diabetes compared to non-diabetic subjects. Also, subjects that started the study with elevated HbA1c contributed predominantly to the change in HbA1c for the entire population.

#### Mean Baseline (BL) vs. 36 month HbA1c

HbA1c (%)	N	Time point	Mean	SD	Range	% Change
Normal BL	176	Baseline	5.40	.033	4.7 - 6.1	
		36 mo	5.49	.037	4.5 - 6.1	-0.09
Elevated BL	48	Baseline	7.55	1.33	6.2-11.8	1.15*
		36 mo	6.40	0.93	5.3 - 9.5	

#### \* P < 0.001 by t-test analysis

Normal reference range = 4.3-6.1% HbA1c

215 subjects had a HbA1c level within normal range at baseline but only 176 had HbA1c test data at 36 months. 60 subjects had a HbA1c level outside normal range at baseline but only 48 had HbA1c test data at 36 months.

Thirteen (13) of the 42 subjects with a BMI = 35 and < 40 reported a pre-implantation history of diabetes (i.e., listed as Diabetes Mellitus, Insulin Resistance, or Glucose Tolerance Impaired). Only nine (9) subjects had HbA1c test data at 36 months post-implantation. There was a statistically significant (p=0.024) reduction in HbA1C at three years.

Mean Baseline vs. 36 months HbA1c test data for subjects with BMI = 35 and < 40

# of subjects	Time point	Mean, % HbA1c	SD	Range	% Change
9	Baseline	7.40	2.0	5.5 <b>- 1</b> 1.8	1 01*
	36 mo	6.39	1.2	5.5 – 9.5	1.01*

<sup>\*</sup> P = 0.024 by t-test analysis

Normal reference range for HbA1c: 4.3-6.1%

#### **Lipids**

The study population experienced a 22% increase in HDL 36 months after surgery. They also experienced a decrease in LDL, total cholesterol and triglycerides. At the three-year follow-up visit, these improvements were statistically significant (p<0.001).

#### Mean Baseline (BL) vs. 36 month Lipids

Lipid	Baseline	N	Time point	Mean	SD	Range	Change mg/dL (%)
Total Cholesterol <sup>a</sup>	Elevated	105	Baseline	233.8	25.7	201-306	
		İ	36 mo	212.8	34.3	138 - 310	21 (9%)*
	Normal	110	Baseline	175.1	18.1	134 - 200	-1.5 (1%)
			36 mo	176.6	29.9	115 - 279	-1.5 (176)
HDL	Decreased	65	Baseline	34.0	4.3	23 - 39	-11 (25%)*
Cholesterol <sup>b</sup>			36 mo	45.0	10.2	23 - 72	
	Normal	153	Baseline	51.0	8.2	40 - 73	-10.4
			36 mo	61.4	13.7	37 - 109	(20%)*
LDL Cholesterol <sup>c</sup>	Elevated	83	Baseline	156.0	20.5	131 - 209	24.4 (16%)*
			36 mo	131.6	32.5	60 - 219	
	Normal	127	Baseline	103.3	18.1	55 - 130	-0.6(<1%)
			36 mo	103.9	27.3	44 - 171	
	Elevated	24	Baseline	407.6	180.0	256 - 940	201.8 (50)*
Triglycerides d	_		36 mo	205.8	125.3	65 - 541	
	Normal	192	Baseline	141.9	50.5	47 - 248	34.2 (24%)
			36 mo	107.7	42.97	34 - 288	

#### \* P < 0.001 by t-test analysis

<sup>&</sup>lt;sup>a</sup> Normal reference range = 130-200mg/dL. At baseline, there were 135 subjects who had a total cholesterol above the normal range. Of these, 105 subjects had lipid panel data available at baseline and 36 months. At baseline, there were 134 subjects whose baseline total cholesterol was in the normal range. Of these, 110 subjects had lipid panel data at baseline and 36 months.

<sup>&</sup>lt;sup>b</sup> Normal reference range = 40-80 mg/dL. At baseline, there were 84 subjects who had a HDL cholesterol below the normal range. Of these, 65 subjects had lipid panel data at baseline and 36 months. There were 183 subjects whose HDL cholesterol at baseline was in the normal range. Of these, 153 subjects had lipid panel data at baseline and 36 months.

<sup>°</sup> Normal reference range = 0-130 mg/dL. At baseline, there were 106 subjects who had a LDL cholesterol above the normal range. Of these, 83 subjects had lipid panel data at baseline and 36 months. There were 157 subjects whose LDL cholesterol at baseline was in the normal range. Of these, 127 subjects had lipid panel data at baseline and 36 months.

<sup>&</sup>lt;sup>d</sup> Normal reference range = 45-250 mg/dL. At baseline, there were 35 subjects who had a Triglyceride level above the normal range. Of these, 24 subjects had lipid panel data at baseline

and 36 months. There were 235 subjects whose Triglyceride level at baseline was in the normal range. Of these, 192 subjects had lipid panel data at baseline and 36 months.

Further, subjects with a BMI ≥35 and <40 and a pre-implantation history of dyslipidemia experienced a statistically significant improvement (p<0.001) in HDL and triglycerides. This sub-population experienced a 28% increase in HDL and 36% decrease in triglycerides 36 months after surgery.

See ADVERSE EVENTS for safety information collected during the US clinical study.

#### PATIENT COUNSELING

Pre-operative evaluation conducted by a multidisciplinary team, including the referring physician, surgeon, psychologist or psychiatrist, exercise physiologist and dietitian is essential to determine a patient's candidacy for gastric banding surgery and potential for long-term success. Members of this team are responsible for ongoing, post-surgery follow-up care.

The patient must be advised of the following:

- The Band is a tool to assist weight loss; close medical follow-up care is required, and the
  patient must commit to making significant changes in eating habits as long as the Band
  remains implanted.
- There are risks associated with surgery in general, and adverse events are known to result from the use of gastric bands. See ADVERSE EVENTS.
- Frequent, severe vomiting during the first few weeks after surgery can result in Band slippage. A proper diet must be maintained, especially during the early weeks while the stomach heals and secures the Band in place.
- Obstructive symptoms, such as inability to swallow, may develop after a Band adjustment. Counsel patients to contact their physician immediately if obstructive symptoms develop. If a stoma is obstructed, withdraw a sufficient amount of saline from the Band to ensure an adequate stoma. See BAND ADJUSTMENT.
- There are significant dietary restrictions that must be followed after placement of the Band. A dietician should be consulted for proper diet, food preparation and eating techniques at various stages post-surgery. Patients may regurgitate if they make poor food choices, do not chew well, or eat too fast. Dietary supplements may be prescribed to avoid nutritional deficiency. Failure to follow dietary instructions may result in ADVERSE EVENTS.
- Vomiting associated with pain lasting more than 3 hours may indicate a serious complication and the patient should see their surgeon right away. See ADVERSE EVENTS.
- Gastric banding does not result in the same rapid weight loss achieved with gastric bypass procedures. Weight loss should occur at an approximate rate of 0.5 to 1.0 kg (1 to 2 lbs.) per week. Rapid weight loss may result in nutritional deficiency.
- In addition to post-surgical follow-up visits, life-long periodic office evaluations will be required to monitor the need for Band adjustment, nutritional health and possible complications.
- Behavior modifications are an important part of long-term success. Participation in a support group affiliated with the patient's monitoring physician is essential for success.
- Self-adjustment by injecting or removing fluid may result in inappropriate Band tightness, loss of restriction, infection, and other complications. See WARNINGS.

- Non-steroidal anti-inflammatory drugs (NSAIDS) may irritate the stomach and may increase the risk of Band erosion into the stomach.
- Surgery may be required to revise or replace the Band and/or the Injection Port. The Band is not intended to be a lifetime implant.
- A Patient Card must be carried on their person at all times. Provide the patient with a Patient Card that indicates the patient has an adjustable gastric band around the stomach to assist in the treatment of morbid obesity. The card informs other clinicians to consult with the patient's surgeon or other qualified medical professional before prescribing medication or performing any gastric procedure.

#### INSTRUCTIONS FOR USE

Placement of the REALIZE Band requires advanced laparoscopic skills and should not be undertaken by surgeons who do not have these skills. Training in the operative techniques required to implant the Band is mandatory and is available from the manufacturer or its appointed preceptors. Detailed instruction on the surgical technique is provided during training from the manufacturer. The following instructions provide salient points for device use and are not intended to replace comprehensive training. Refer to Illustration 1 for Band nomenclature and Illustrations 2-12 for each of the following steps.

- In addition to standard laparoscopic instruments and equipment, ancillary products are required to implant and use the Band. See ANCILLARY PRODUCTS.
- Keep a second REALIZE Band available in case of iatrogenic damage.

CAUTION: When laparoscopic instruments and accessories from different manufacturers are employed together, verify instrument compatibility prior to surgery. This is because minimally invasive instruments from different manufacturers may vary in dimensions.

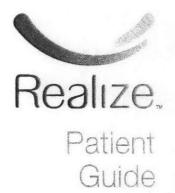
CAUTION: Rarely, conversion from a laparoscopic to an open approach is necessary. Be prepared for this possibility.

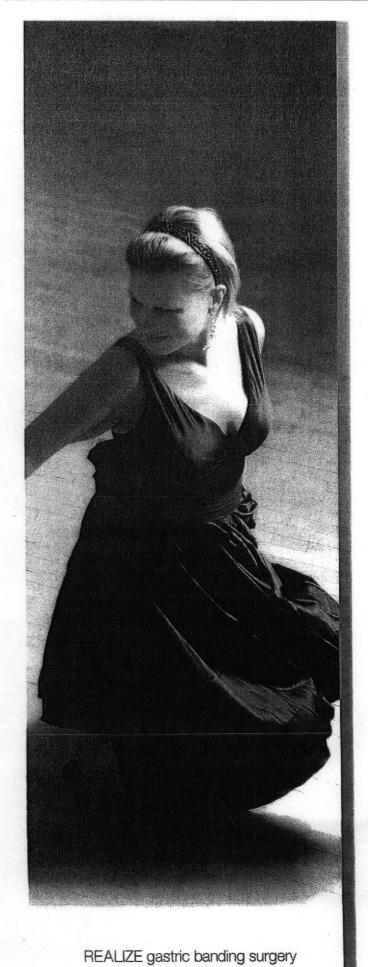
**WARNING:** Band placement after an intraoperative gastric injury may increase the risk of infection.

#### 1. Prepare the Patient.

- Severely obese patients are at increased risk for deep venous thrombosis. Use low dose, subcutaneous heparin or a low molecular weight heparin analogue for antithrombotic prophylaxis in the peri-operative period.
- Position the patient in either supine or modified lithotomy position, or tilt the operating table in a moderate head-up (reverse Trendelenburg) position to enhance visualization of the stomach.
- Establish pneumoperitoneum, and position trocars using standard laparoscopic techniques for peritoneal exposure and visualization. Position a 15 mm trocar at the location for Band insertion.

**WARNING:** Placing the Band through a trocar smaller than 15 mm may damage the Band.







on September 25, 2003

REALIZE is a trademark of Ethicon Endo-Surgery.

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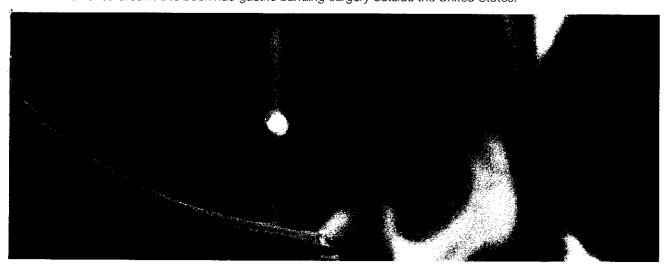
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Patients featured in this book had gastric banding surgery outside the United States.



### Glossary

<del>)</del>

Abdominal wall: The muscles and connective tissue that extend from the ribs to the pelvis.

Bariatric surgery: Weight loss surgery.

**Barium**: A compound that shows up on X-ray and fluoroscopy. When you swallow a drink that contains barium sulfate, a fluoroscope tracks the barium's path through your digestive system.

**Barrett's esophagus**: A condition in the esophagus that is associated with an increased risk for esophageal cancer.

**Biocompatible**: A material that is not harmful or toxic to living tissue.

**Carbon dioxide gas:** A natural gas in the atmosphere that is also exhaled by humans.

**Chronic pancreatitis**: Ongoing inflammation of the pancreas that changes the normal structure and function of the pancreas.

**Cirrhosis of the liver**: A consequence of ongoing liver disease causing damage and scarring in the liver that leads to the loss of liver function.

**Clinician**: A healthcare professional such as a surgeon, physician, nurse, dietician, or X-ray technician.

Deep vein thrombosis: Blood clot.

**Esophageal dysmotility**: Inability of the esophagus to move properly, making it difficult to swallow.

**Fluoroscopy**: A video image similar to an X-ray that shows real-time movement of internal organs.

**Healthcare team**: This team may include your bariatric surgeon, primary care physician, psychological counselor, dietician, weight management center, and fitness expert.

Hemoalobin: The protein in red blood cells that carries oxygen to the lungs and tissue.

Hiatal hernia: A condition when the stomach bulges into the chest through an opening in the diaphragm.

Incision: A surgical cut made in the skin and underlying tissue.

Laparoscopic surgery: Minimally invasive surgery in the abdomen.

Mean: The arithmetic average; also called the arithmetic mean.

Percent of excess weight loss (%EWL): A number that evaluates weight loss over a period of time. The number is calculated in two steps: 1) dividing actual weight loss by ideal weight loss, then 2) multiplying by 100 percent.

Portal hypertension: High blood pressure in the large vein that carries blood from the digestive tract to the liver (portal vein); often occurs as a result of cirrhosis.

> **Pulmonary embolism:** A sudden blockage of a lung artery by material circulating in the blood; most often a blood clot from a deep vein in the lung or pelvis.

Regurgitate: To cause backward flow of food from the upper stomach.

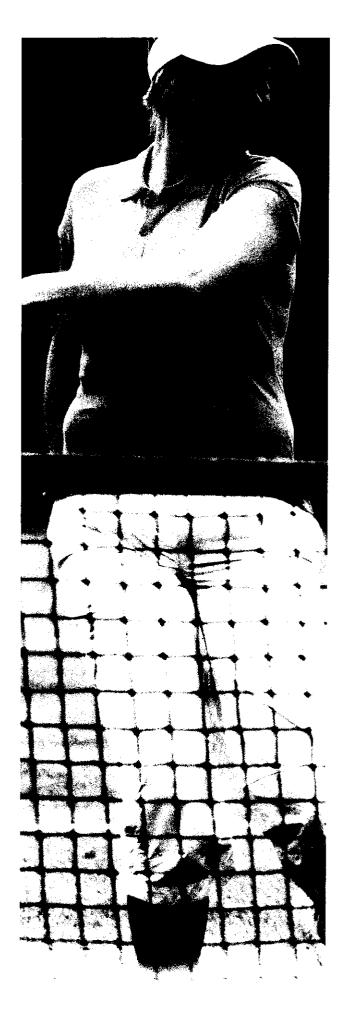
Saline: A safe fluid frequently used in intravenous drips (IVs).

**Septum**: A sturdy silicone layer located at the top of the injection port.

**Silicone**: A solid, soft, and flexible material that does not contain gels or fluids.

**Stoma:** The location where the band is wrapped around the stomach. This placement creates a tight junction (passage) between the upper and lower stomach chambers.

**Stoma obstruction**: Stoma blockage.



### Welcome

Welcome to a safe, effective, and healthy way to achieve significant long-term weight loss. We are here to tell you about the REALIZE Adjustable Gastric Band, a surgical implant approved by the U.S. Food and Drug Administration (FDA) for weight reduction in individuals suffering from morbid obesity. The purpose of this book is to give you information about the REALIZE Band and provide a framework for future discussions with your healthcare team about whether the REALIZE Band is right for you.

As you read this book, you will learn about the REALIZE Band and:

- How it works to control the amount of food you can eat
- How it is placed during minimally invasive gastric banding surgery
- Why you feel full sooner and longer with a REALIZE Band
- c Its benefits and risks
- Your role in maximizing its effectiveness

### The REALIZE Band's History



Swedish Band developed at Huddinge University Hospital, Sweden. Your struggle with weight and coexisting health issues may have caused you to lose hope, feel out of control, and think there is no solution. But we want you to know that the REALIZE Band brings true hope for a healthy life.

The REALIZE Band was first developed in Europe after years of research. It has been safely helping people outside the United States lose weight and gain control of their health for more than 10 years. Its materials were chosen

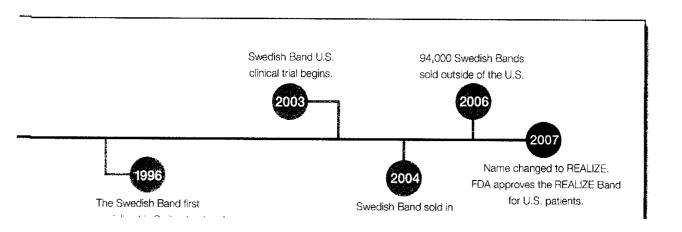


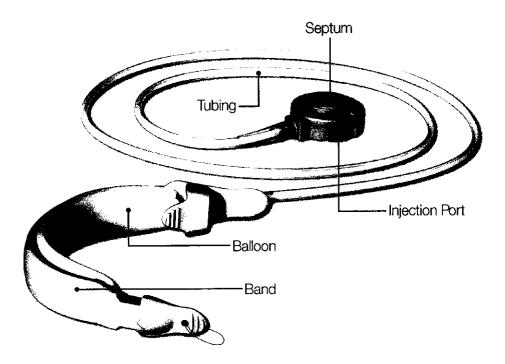
with your safety and comfort in mind. So far, more than 100,000 people outside the United States have used one of our gastric bands to manage their weight; and now, with FDA approval, the REALIZE Band is available in the United States. This means that we can work together as you improve your health.

<u>Underlined</u> words are defined at the bottom of each page and in the Glossary on pages 4 and 5.

#### Glossary Terms -

Healthcare team: This team may include your bariatric surgeon, primary care physician, psychological counselor, dietician, weight management center, and fitness expert.





# The REALIZE™ Band

The REALIZE Gastric Band is actually two medical devices that are implanted at the same time during surgery. The first implant, the REALIZE Band, wraps completely around the upper part of the stomach. The second implant, the REALIZE Injection Port, is attached to the <u>abdominal wall</u> underneath the skin. The injection port is used to add <u>saline</u> to the band after surgery. The two implants are connected by way of soft, thin, hollow tubing. The REALIZE Band and the REALIZE Injection Port, including the tubing, are made entirely from <u>biocompatible</u> materials.

#### Band

The band is a strong, flexible <u>silicone</u> structure that fits securely around the upper stomach. The inside of the band has a soft balloon that comes in direct contact with the stomach. The balloon can hold up to 9cc (1.8 teaspoons) of saline. The amount of saline in the balloon controls tightness (restriction) around the stomach. In turn, the amount of restriction affects how much food can be eaten during a meal and the length of time it takes food to progress through the digestive system. This means you will feel full sooner and stay full longer with a REALIZE Band.

#### Glossary Terms

Abdominal wall: The muscles and connective tissue that extend from the ribs to the pelvis.

**Saline**: A safe fluid frequently used in intravenous drips (IVs).

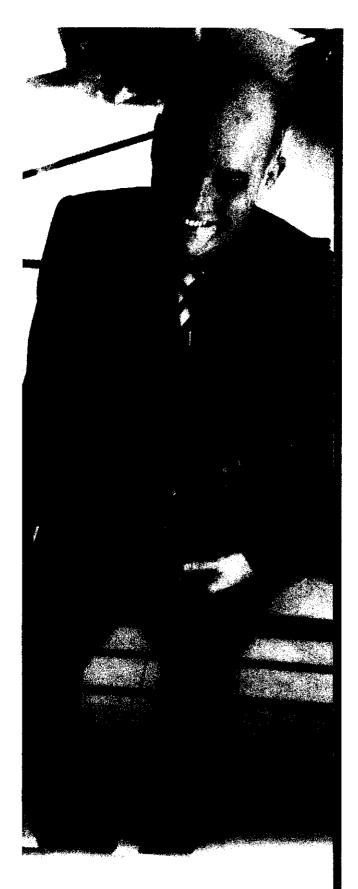
Silicone: A solid, soft, and flexible material that does not contain gels or fluids.

When the band is implanted, it molds the stomach into two connected chambers: a small upper stomach and the lower stomach. You will not be able to feel the band by pressing on your stomach. We will tell you more about the band in the sections Gastric Banding Surgery and How the REALIZE Band Helps You Lose Weight.

#### Injection Port

The REALIZE Injection Port is made from an implant-grade medical plastic. The top of the port has a sturdy silicone layer called a <u>septum</u>. During band adjustments, saline is injected with a needle into the port through the septum. The bottom of the port is attached to the abdominal wall with fasteners or stitches (sutures) that do not dissolve.

The port is fastened to the abdominal wall underneath layers of skin and tissue. It is only about 1/2 inch high and is completely enclosed inside the body. You may be able to feel the port by gently pressing on your abdomen. Otherwise, you should not be aware of its presence. Soft, thin tubing connects the band and the port. We'll tell you more about the port in the section **REALIZE Band Adjustments**.



REALIZE gastric banding surgery on June 10, 2006

## The Digestive System

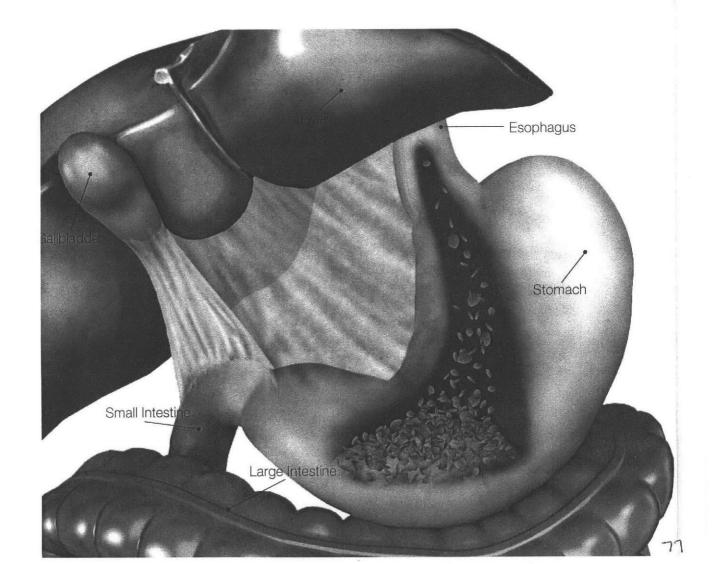
To understand how the REALIZE Band works, you need to know how the digestive system works. The illustration on the opposite page shows what a typical person's anatomy looks like while food is being consumed.

When a person begins to eat, digestive juices in the mouth start to break down food. Chewing food well is an important part of the digestive process. After swallowing, food travels down the esophagus directly to the stomach. Food collects, starting at the bottom of the stomach. Strong digestive juices in the stomach break down food so that the small intestine can absorb nutrients in the food. Food leaves the stomach and enters the small intestine.

REALIZE gastric banding surgery on April 12, 2005

While food is in the first part of the small intestine, it is mixed with bile from the gallbladder and other juices from the pancreas. Food moves along the small intestine, where nutrients in the food are absorbed and turned into energy to fuel the body. After nutrients are removed, the remaining food moves into the large intestine, which is also called the colon. From here, waste is eliminated from the body. You may be interested to know that when a person has his or

her gallbladder removed, digestion continues the same path. The difference is that bile, which is produced in the liver, is no longer stored in the gallbladder. Instead, bile gets added to digestive juices directly from the liver.

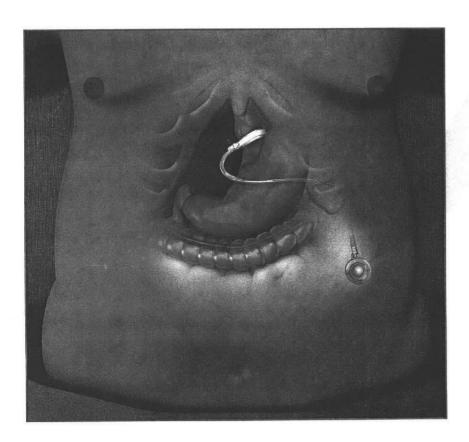


# **Gastric Banding Surgery**

Gastric banding is a specific type of <u>bariatric surgery</u>. During gastric banding surgery, a gastric band is wrapped around the upper stomach to **limit** food intake and **slow** the progress of food through the digestive system. No part of the stomach is stapled or removed. The intestines are not rerouted, the small intestine can absorb nutrients from food, and waste can be eliminated in the normal manner.

The REALIZE Band is implanted using <u>laparoscopic surgery</u> through several small <u>incisions</u>. The actual location and number of incisions may vary. The surgeon chooses incision locations depending upon individual anatomy and previous abdominal surgeries.

To perform laparoscopic surgery, a small incision (less than 1 inch) is made near the navel and the abdomen is filled with <u>carbon dioxide gas</u> to create a work space for the surgeon. The gas is safe and occurs naturally in the body. Then, a small laparoscopic camera is placed through another small incision and into the abdomen. The camera sends a picture of the stomach and the abdominal cavity to a video monitor.



A few additional small incisions are made in the abdomen. The surgeon watches the video monitor and works through these small incisions to operate on the stomach. The surgeon creates a small circular tunnel behind the stomach and then inserts the band through the tunnel and locks the band around the stomach.

Next, the tubing is connected to the port and the port is Profile view of port

fastened to the abdominal wall underneath layers of skin and tissue. It usually takes a surgeon less than

one minute to attach the REALIZE Injection Port. The port is usually fastened (or sutured) on the left or right side, about 2 inches below the rib cage. The exact location depends upon each person's body shape and the surgeon's decision. At the end of surgery, the carbon dioxide gas escapes from the incisions. Then, all incisions are closed with stitches or liquid skin adhesive (an alternative to stitches). The injection port incision is usually 1 to 2 inches long. The other incisions are less than 1 inch. Total

surgery time is usually between 30 minutes and one hour.

The REALIZE Band is intended to be a long-term implant. At this time, there is no evidence to suggest that the REALIZE Band will need to be replaced, except in the event of a complication (see Risks). Even so, there is no guarantee that the REALIZE Band will work without fault for the rest of your life. We cannot assume any liability or responsibility for physiological reaction to the material, general wear of the balloon over time, or similar reasons. Because gastric banding surgery does not permanently alter stomach and intestinal anatomy, the REALIZE Band can be removed if necessary. Reversal surgery is not simple and weight gain is usually observed in people who have their band removed.

Glossary Terms

Bariatric surgery: Weight loss surgery.

Incision: A surgical cut made in the skin and underlying tissue.

Laparoscopic surgery: Minimally invasive surgery in the abdomen.

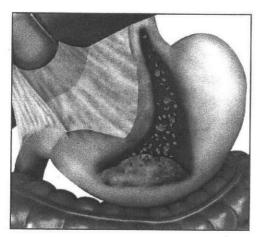
Carbon dioxide das: A natural das

# REALIZE gastric banding surgery on January 24, 2005

# How the REALIZE™ Band Helps You Lose Weight

When the REALIZE Band is implanted, it molds the stomach into two connected chambers: a small upper stomach and the lower stomach. The place where the band is wrapped around the stomach creates a junction between the stomach chambers. This junction is called a <u>stoma</u>. The amount of restriction (tightness) at the stoma is controlled by using the REALIZE Injection Port to increase or decrease the amount of saline in the band. The ability to change the restriction is why the REALIZE Band is called an *adjustable* gastric band. You will learn more about restriction in the section on **REALIZE Band Adjustments**.

The REALIZE Band limits the amount of food you can eat at one time. The new upper stomach can only hold about 4 ounces (1/2 cup) of food. For this reason, you will feel full sooner than usual. The lower stomach does not need to fill for you to feel full. The stoma created by the band also slows the flow of food from the small upper stomach to the lower stomach. When the stoma is made smaller (restriction is increased), you can eat less food during a single meal and food will empty more slowly to the lower stomach. This means you will feel full sooner and stay full longer with the REALIZE Band and will have better control of your appetite. Although the REALIZE Band can help you feel full faster and stay full longer, it will not eliminate the emotional desire to eat.





Normal Stomach

Stomach with REALIZE Band

If you try to eat more than 4 ounces at a meal, you may feel uncomfortable and may regurgitate. This reaction is common, but is due to inappropriate eating behaviors. You quickly will learn how to eat to avoid discomfort and regurgitation. As you eat less food, your body will stop storing excess calories and it will begin to use its fat energy stores. The goal is to lose a healthy 1 to 2 pounds a week.

In general, you only notice the band's presence around your stomach when you are eating. However, there are times when some people temporarily feel increased band restriction. These times may occur in the morning, during allergy season, when under extreme stress, during a menstrual cycle, or with a significant increase in altitude.

The REALIZE Band provides you with a powerful tool to combat hunger and overeating. It helps you feel full faster and longer. But if you eat high-calorie foods or drink highcalorie liquids, the REALIZE Band will not promote weight loss. For this reason, you will need to follow specific eating and behavioral guidelines to lose weight. Your healthcare team will provide you with specific guidelines to help you accomplish your goals. General guidelines are discussed in the section The REALIZE Band Lifestyle.

# **REALIZE™** Band Adjustments

The REALIZE Adjustable Gastric Band comes in one size and is tailored to your individual needs throughout the adjustment process. Adjustments may be necessary as long as you have your gastric band. Adjustments are not additional surgeries. An adjustment can be performed at a healthcare professional's office, clinic, or hospital. During adjustments, saline is added to (or removed from) the band by way of the port. Saline travels from the port through the tube and into the band.

People with a gastric band often refer to adjustments as "fills" when saline is added. Fills tighten the band to increase the amount of restriction at the stoma. You will feel full sooner and longer than before a fill because food will empty from your upper stomach more slowly.

When the REALIZE Band is implanted, it does not contain any saline, but a small amount of restriction is achieved even with an empty band. After surgery, the stomach needs time to heal before you can have a band adjustment. This usually takes four to six weeks. In general, you probably will be ready for your first adjustment after you have been eating solid food for about a week. If you are losing 1 to 2 pounds a week and are feeling satisfied with an appropriate portion of food, you may postpone your adjustment until another follow-up visit. The entire adjustment process usually takes five to 10 minutes.

# The Four Steps to an Adjustment

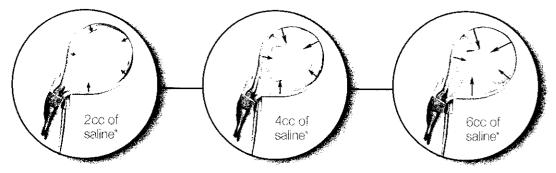
- 1. Preparing for an adjustment: You will need to have an empty stomach each time you have a band adjustment. For this reason, you should not eat any soft or solid food for at least two hours before an adjustment. You will not be asked to change into a hospital gown, so wear clothing that will allow you to easily show your abdomen.
- 2. Locating the REALIZE Injection Port: The <u>clinician</u> uses one of two methods to locate the port. Sometimes a special video image, called <u>fluoroscopy</u>, is used. Other times, the clinician will find the port by gently pressing on your abdomen. The REALIZE Injection Port usually takes a minute or less to locate this way.
- 3. Inserting (or removing) saline: The clinician will disinfect your skin. He or she will insert a fine needle through your skin down into the port. The REALIZE Injection Port's large septum improves the clinician's ability to locate the septum with the needle. During a fill, a specific amount of saline, usually 0.5cc to 1.0cc, will be injected into the port (as shown in the picture on the opposite page). Saline is safe and is a substance that occurs naturally in your body. The REALIZE Injection Port has puncture-resistant protection near the tubing connection. This minimizes the risk of needle puncture at the tubing.

4. Checking band tightness: Finally, the clinician will check your band tightness. You may be asked to drink one full swallow of barium while a technician takes a fluoroscopic image of your stomach; or you may simply be asked to take small sips of water to make sure you can swallow. A word of caution: If you regurgitate within 48 hours after a fill, or if food gets stuck in your upper stomach, you will need to contact your surgeon right away. These symptoms may indicate your band is too tight.



After an adjustment, you probably will return to liquids for a day, then soft foods for one or two days. People who have a band say that, during a meal, they can feel more restriction for one or two days after an adjustment.

At each adjustment visit, a small amount of saline will be added until you are able to lose weight at a satisfactory rate without experiencing uncomfortable side effects (discussed in the section on Risks). When this occurs, you have found your ideal fill level. This is the point where the amount of saline in the band is just right for you. This amount is different for each individual. Remember, the REALIZE Band is tailored to your individual anatomy. Your ideal fill level might be 2cc of saline, while another person's ideal fill level might be 6cc of saline. Focus on losing a healthy 1 to 2 pounds a week rather than the amount of saline in your band. The REALIZE Injection Port is about 1/2 inch high. This height will minimize the port's bulge underneath the skin (protrusion) as you start to lose weight.



Your ideal fill level may change as you lose weight. If you notice that you can eat larger quantities of food without uncomfortable side effects, talk to your clinician. This may indicate that you need to have another REALIZE Band adjustment.

#### Glossary Terms

Barium: A compound that shows up on X-ray and fluoroscopy. When you swallow a drink that contains barium sulfate, a fluoroscope tracks the barium's path through your digestive system.

Clinician: A healthcare professional such as a surgeon, physician, nurse, dietician, or X-ray technician.

Fluoroscopy: A video image similar to an X-ray that shows real-time movement of internal organs.

<sup>\*</sup> These illustrations show how the band would appear while wrapped around the stomach.

# **Gastric Banding Indications**

Before we go any further in our discussion, you need to know whether the REALIZE Adjustable Gastric Band is an appropriate weight loss tool for you. There is no upper weight limit for the REALIZE Band; however, you should meet several qualifications for gastric banding surgery.

First, according to the National Institutes of Health, you may be a candidate for surgery if you:

Meet at least one of the two following criteria:

☐ Have a Body Mass Index (BMI)\* of at least 40

or

☐ Have a BMI of at least 35 with one or more serious obesity-related condition

and meet both of the following criteria:

☑ Have failed more conservative weight loss alternatives, such as supervised diet, exercise, and behavior modification programs

and

☑ Are at least 18 years of age

These are not the only things you need to consider as you discuss the REALIZE Band with your surgeon. You also need to think about your determination and practical ability to make some serious changes in the way you live your life, not just the way you eat. The REALIZE Band is a tool to help reconstruct and improve your health. As with any new tool, you must actively learn how to use the tool to get the best benefits.



<sup>\*</sup> If you do not know your BMI and ideal weight, you can go to www.RealizeBand.com, or call 1-866-REALIZE (1-866-732-5493).

# **Gastric Banding Contraindications**

If you meet the *indication* criteria for gastric banding surgery, your surgeon will evaluate your medical history for any conditions that might put you at increased risk during or after surgery. Situations where the **risks are greater than the benefits** that would be gained from surgery are *contraindications*. Please check all that apply to you.

Inflammation of the digestive tract, including ulcers, severe esophagitis, or Crohn's disease		
Severe heart or lung disease		
Upper digestive tract bleeding conditions due to enlarged or fragile veins		
Portal hypertension		
Abnormal digestive tract anatomy		
Cirrhosis of the liver		
Chronic pancreatitis		
Infection of any type, anywhere in your body		
Known allergies to the implant materials		
Using steroids for a long period of time or within 15 days of surgery		
Currently pregnant		
Younger than 18 years of age		
Unwilling to make significant changes in eating and behavior patterns		
Conditions or behaviors that would make it difficult to appropriately follow directions		

If you have checked any of the above conditions, please tell your surgeon.

## Glossary Terms -

Chronic pancreatitis: Ongoing inflammation of the pancreas that changes the normal structure and function of the pancreas.

Cirrhosis of the liver: A consequence of ongoing liver disease causing damage and scarring in the liver that leads to the loss of liver function.

Portal hypertension: High blood pressure in the large vein that carries blood from the digestive tract to the liver (portal vein); often occurs as a result of cirrhosis.

# Warnings

Even when the best product, the most skilled surgeon, and the finest medical staff are available, every surgical device and every surgical procedure has the potential for some serious adverse outcomes. For this reason, we want to warn you of these serious events.

Death can occur during or soon after any surgery, even when every precaution has been taken. There was one death in the U.S. clinical study. The cause of death was probably related to port replacement surgery.



If you have a hiatal hernia, it may need to be repaired before or during gastric banding surgery. This is because an unrepaired hiatal hernia may make proper band placement difficult and increase the risk of band slippage.

If you have an esophagus that is unable to move properly (esophageal dysmotility) or an abnormal condition in the esophagus (Barrett's esophagus), you may be at a higher risk for complications after surgery, including a reoperation. Use of the REALIZE Band in a patient with Barrett's esophagus is a balance between the patient's need for the gastric band and the severity of the disease.

Some types of emotional or mental conditions may make gastric banding inappropriate. A psychological counselor is qualified to make this determination.

Food may get stuck in the stoma or upper stomach, especially after a band adjustment. If the food does not pass into your lower stomach or you have abdominal pain that lasts more than three hours, you need to contact your surgeon right away.

## **Precautions**

Although there are risks associated with gastric banding surgery, you may reduce some of these risks, and possibly improve your results, by selecting a surgeon who:

- Has advanced laparoscopic skills and experience with bariatric surgery
- Has specific training and experience with the REALIZE Band
- Provides a healthcare team to help you develop a lifestyle plan for successful weight management
- Is committed to your long-term follow-up

### and

 Discusses with you the potential risks, complications, and benefits of gastric banding surgery



REALIZE gastric banding surgery on May 31, 2005

## **Risks**

There are risks associated with gastric banding surgery. You can think of risks in the following way. Some are associated with abdominal surgery, some are specific to a gastric band, and some may be unique to you. Your weight, age, and medical history play a significant role in determining your specific risks. If you have health conditions such as heart disease or diabetes, or if you are on certain medications (such as blood-thinning medications) or have had other surgeries, your surgeon will inform you about your specific risks for gastric banding surgery.

During the U.S. clinical study of 276 patients, we documented all reported complications in order to evaluate the safety of the REALIZE Adjustable Gastric Band. The sections below provide specific information regarding the complications that were reported.

## Risks Associated with Abdominal Surgery

Risks are associated with any type of surgery, including abdominal surgery. These risks are greater for individuals who suffer from obesity. Laparoscopic surgery reduces some of these risks compared to open surgery. But laparoscopic surgery is not appropriate for some people. The decision to perform open surgery is a judgment made by your surgeon either before or during the actual operation. This decision is based on patient safety. In the U.S. clinical study, 275 out of 276 (99.6 percent) patients were able to have their gastric band implanted using laparoscopic surgery.

Risks associated with any general abdominal surgery include bleeding; pain; shoulder pain; pneumonia; complications due to anesthesia and medications; <u>deep vein thrombosis</u>; injury to the stomach, esophagus, or surrounding organs; infection; <u>pulmonary embolism</u>; stroke or heart attack; and death.

## Risks Associated with Gastric Banding

Some risks are associated with any adjustable gastric band and complications can occur after the surgery is completed. These complications are not usually life threatening.

Patients in the U.S. clinical study reported complications associated with gastric banding. Complications that were considered serious and occurred in more than 2 percent of the patients (six or more patients) were: migration of implant, which includes band erosion, band slippage, and port displacement, 5.4 percent (15 patients); and tubing-related complications, which include port disconnection and tubing kinking, 5.1 percent (14 patients). There was one reported band erosion in the U.S. clinical study.

The non-serious complications reported in more than 5 percent of the patients (14 or more patients) were: back pain, chest pain, constipation, depression, diarrhea, difficulty while swallowing, fatigue, flatulence, general abdominal pain, GERD (gastroesophageal reflux disease), hair loss, headache, hypertension, inflammation of the nasal passages, inflammation of the sinuses, influenza, insomnia, joint pain, pain after surgery, port site pain, nausea, upper abdominal pain, upset stomach, upper respiratory tract infection, urinary tract infection, and vomiting. There were other non-serious complications that occurred in less than 5 percent of the patients (less than 14 patients).

Complications may result in reoperations. In the U.S. clinical study, there were 43 reoperations. Two of these reoperations were elective and were not related to a complication.

## Side Effects and Discomfort

After surgery your body needs to adjust to the newly implanted REALIZE Band. Your recovery experience may not be the same as other REALIZE Band patients. Regurgitation, nausea, acid reflux, constipation, and diarrhea are typical. But abdominal pain that lasts more than three hours means that you need to contact your surgeon right away.

People who lose a lot of weight, regardless of the weight loss method, are at a high risk for developing gallstones. This may lead to surgery to remove the gallbladder. There may be other side effects that are specific to you. You should report any unusual experiences to your surgeon.

Glossary Terms -

Deep vein thrombosis: Blood clot.

Pulmonary embolism: A sudden

Stoma obstruction: Stoma blockage.

### BENEFITS | 24

## **Benefits**

The FDA approved the REALIZE Band for use in the United States based upon results from a three-year clinical study. The study began with 276 patients, and 228 completed the study.

Results show that 224 patients lost a <u>mean</u> of 40 percent of their excess weight at one year. By the end of the second year, 212 patients lost 45 percent of their excess weight. By the end of the study, the majority of the patients had maintained their <u>percent of excess weight loss (%EWL)</u>. Additionally, patients were able to reduce their (average) BMI from 44 to 36 in the first year after surgery. Patients were able to maintain their reduced BMI through their third year. Please see page 27 for an explanation of how to calculate %EWL.

## Weight Loss Over Time

FOLLOW-UP VISIT	NUMBER OF PATIENTS	%EWL	WEIGHT LOSS IN POUNDS	ВМІ
Presurgery	228	0%	Olbs	44
Four to six weeks	224	16%	20lbs	41
Six months	220	30%	38lbs	38
One year	224	40%	50lbs	36
18 months	213	44%	55lbs	35
24 months	212	45%	57lbs	35
36 months	228	43%	53lbs	36

## Weight Loss at Three Years\*

%EWL AT THREE YEARS	NUMBER OF PATIENTS	PERCENT OF PATIENTS	
Gained weight	5	2%	
0% to 5%	6	3%	
5% to 25%	41	18%	
25% to 33%	33	14%	
33% to 50%	63	28%	
50% to 75%	56	25%	
75% to 100%	24	10%	
	228	100%	

<sup>\*</sup> These data were extrapolated from Table 9.1 of the Tables and Listings from the U.S. clinical study. Of the 276 patients who started the study, 2% (six patients) gained more than 5% of their EWL at three years; 3% (eight) had no change; 20% (56) lost between 5% and 25% EWL; 75% (206) lost at least 25% EWL; 60% (166) lost at least 33% EWL; 33% (91) lost at least 50% EWL; and 9% (26) lost at least 75% EWL.

The study found differences in %EWL based on gender. For patients who completed the study, the average (mean) %EWL at three years was 35.8 for males (38 patients) compared to 44.7 for females (126 patients). The study target of 32.6 or more %EWL at three years was met for both gender groups. Your results may vary.

## Improvements in Obesity-Related Conditions

- Scientific literature supports that weight loss in obese patients with type 2 diabetes aids in the control of the disease. In the clinical study, patients who had diabetes and an elevated level of a form of <a href="https://example.com/hemoglobin">hemoglobin</a> (HbA1c) in their blood prior to surgery had their level of this form of hemoglobin drop below 7 percent after losing weight with the REALIZE Band. Clinical study patients who had diabetes and a normal hemoglobin (HbA1c) level in their blood prior to surgery maintained values below 7 percent after surgery. The American Diabetes Association® (ADA) considers diabetes to be under control when this particular form of hemoglobin is 7 percent or less.\*
- The clinical study patients experienced a 22 percent increase (10mg/dl) in good cholesterol (HDL) 36 months after surgery. They also experienced a decrease in bad cholesterol (LDL), total cholesterol, and triglycerides. At the three-year follow-up visit, these improvements were statistically significant.

<sup>\*</sup> Rohlfing CL, Wiedmeyer HM, Little RR, et al. Defining the relationship between plasma glucose and HbA1c. Diabetes Care 2002 Feb;25(2):275-8.

## Improvement in Quality of Life

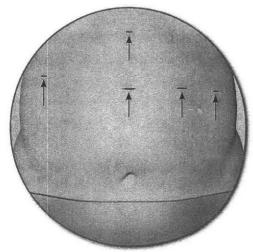
Patients in the U.S. clinical study reported improvements in various aspects of their quality of life. To evaluate these improvements, patients completed a written evaluation that measured various aspects of their mental and physical health.

- 68.8 percent (154 patients) reported their general health to be much better one year after surgery.
- Patients reported a significant improvement in their vitality, mental health, and social functioning three years after surgery.
- Patients reported a significant improvement in the physical aspects of their quality of life three years after surgery. This included improvement in general health, reduction in bodily pain, and increased ability to complete daily and work activities.

These results show that gastric banding surgery can be effective for people who choose to transform their health with the REALIZE Band.

## Benefits of Laparoscopic Surgery

Another important benefit of gastric banding surgery is that it can be performed in a minimally invasive manner. Laparoscopic surgery is usually shorter in duration; there are no large incisions; it is less painful; and it allows you to go home from the hospital sooner. The illustrations below show the difference between laparoscopic and open surgery.



Laparoscopic Gastric Banding Surgery



Open Abdominal Surgery

# HOW TO CALCULATE PERCENT OF EXCESS WEIGHT LOSS

When we conducted the clinical study, the FDA asked us to follow patient weight loss using a method called percent of excess weight loss (%EWL). This method takes actual weight loss and divides by ideal weight loss to get a percentage.

For example, suppose a woman is 5'8" and weighs 300 pounds. At 5'8", her ideal weight is 154 pounds. So, her ideal weight loss is 300 minus 154 = 146 pounds. Now, suppose that she has lost 50 pounds since her gastric banding surgery. Her %EWL is 50/146 = 34 percent. If she loses all 146 pounds, then her %EWL is 100 percent. Your ideal weight is based on your height, and this chart can be found at www.RealizeBand.com.





# Your Transformation Begins

People who attain significant weight loss and better health with the REALIZE Adjustable Gastric Band have certain things in common. We call these "Success Factors." When you are willing to make these Success Factors part of your life, you put yourself in an excellent position to reach your goals. We will talk about these Success Factors in the following three sections: Planning and Preparing for Surgery, A Safe and Healthy Recovery, and The REALIZE Band Lifestyle. With each success, you can build confidence, regain hope, and control your life.

## These Success Factors Are:



Educate yourself. Learn the risks, requirements, and rewards of each surgical weight loss option.



Surround yourself with a support network of people who want you to succeed.



Start practicing your new eating and exercise behaviors before surgery.



Give your body time to heal by following your healthcare team's recovery plan.



Eat and drink in a new way. This means smaller portions and appropriate food choices.



Exercise to reach your goals.



Listen to your REALIZE Band and pay attention to the signals it sends to your body.



See your healthcare team on a regular basis for adjustments and follow-up care.

# Planning and Preparing for Surgery

## Make Your Decision



Educate yourself. Learn the risks, requirements, and rewards of each surgical weight loss option.

- When you do this, you know your options for significant, long-term weight loss and can prepare for the journey ahead.
- c If you are interested in transforming your health with the REALIZE Band, work with a team of healthcare professionals. This team may include your bariatric surgeon, primary care physician, psychological counselor, dietician, weight management center, and fitness expert.
- You and your healthcare team will determine if the REALIZE Band is right for you depending upon your physical, emotional, and psychological evaluation prior to surgery. Together you will develop a lifestyle plan for successful weight management. Once you make your decision, you can get ready for your new, healthy life.

# Begin Your New Lifestyle



Surround yourself with a support network of people who want you to succeed.

- This network includes your healthcare team, family, and friends.
- Attend virtual or live support groups where people share their experiences and where you can be comfortable with others who understand you.



Start practicing your new eating and exercise behaviors before surgery.

- It takes time to become accustomed to life with the REALIZE Band. So get a head start by practicing your new eating and exercise behaviors early.
- in The REALIZE Band Lifestyle.
  Think of this as a warm-up routine in the same way an athlete does stretches before an athletic event or a musician practices before a concert.
- Develop and implement strategies to help you cope with times when you know you are vulnerable to emotional or unhealthy eating behaviors.

P Make your decision

P Begin your new lifestyle

# Prepare for the Day of Surgery

Your healthcare team will give

you a specific set
of instructions to
prepare you for
surgery. They
know your
specific clinical
needs and may
give you information

that is different from the information provided in this booklet. In that situation, *always* follow your healthcare team's directions and advice.

- You may start a high-protein liquid diet. This diet will improve your surgeon's ability to see your stomach during surgery.
- You also may start taking vitamins and minerals at this time. Your healthcare team will determine whether you need to continue taking nutritional supplements after surgery.

## The Day of Surgery

- When you go to the hospital, wear comfortable clothes and shoes that will be easy to put on when you are ready to go home.
- Take two pillows to the hospital. You may want these to wrap around your stomach for comfort during the car ride home.
- Bring someone with you who can make decisions for you while you are under general anesthesia (asleep).
- Total surgery time is usually between 30 minutes and one hour. Refer to Gastric Banding Surgery for a description of the surgery.
- Several hours after surgery you may get up, sit in a chair, and walk a short distance.
- Once you awake after surgery, you probably will take liquid pain medication by mouth for any discomfort.
- A clinician will test your ability to swallow. When you can drink liquids, you probably will be ready to go home. Most people go home the day of surgery or the following day.

Prepare for the day of surgery

Day of surgery

# A Safe and Healthy Recovery

## Recovery Guidelines



Give your body time to heal by following your healthcare team's recovery plan.

Recovery may last six to eight weeks. Healthy recovery is critical to safety and success with your REALIZE Adjustable Gastric Band. The recovery plan presented here is general and may be different from the one your healthcare team recommends. There also may be differences in what you eat and do if you are diabetic, or have a heart condition or some other health restriction. As always, follow your healthcare team's directions.

## Recovery at One to Two Weeks

Progress from a clear liquid diet to a full liquid diet as the swelling from surgery goes away. Your healthcare team will provide advice on the quantity and types of liquids that are right for you at this stage.

- Slowly sip at least 64 ounces of lowcalorie, non-carbonated fluids each day to stay hydrated.
- Avoid alcohol and carbonated beverages.
- Do not worry if you have shoulder pain. A few days after any type of abdominal surgery many people have pain that radiates to the shoulder and neck. This is normal and the pain will go away in a few days.
- Stay mobile. Pneumonia and blood clots are two risks for anyone who has had surgery. Reduce these risks by moving around. Start taking walks or use a treadmill.
- Use caution when bending at the waist and picking up heavy objects. If you injure your abdomen, you may lengthen your recovery period.
- Your healthcare team will advise you when to return to work and when to resume prior activities. Of course, this timing depends on your type of employment, the required physical activity, and your recovery progress.

Pecovery

## Recovery at Three to Six Weeks

- Begin eating soft foods and progress toward solid foods. Your healthcare team will provide advice on the quantity and types of food that are appropriate at this stage so you can maintain healthy and balanced nutrition.
- Slowly sip 64 ounces of low-calorie, non-carbonated liquids each day to stay hydrated.
- Avoid raw vegetables, fruits with skin, nuts, popcorn, tough meats, stringy foods, and crusty bread (bagels and pretzels). These may block your stoma.
- Avoid alcohol and carbonated beverages.
- If you feel nauseated or regurgitate when you start eating soft foods, go back to your liquid diet and wait a few more days before trying soft foods. Abdominal pain that lasts more than three hours means that you need to contact your surgeon right away.

- Continue walking and add aerobic exercises such as cycling, jogging, and swimming. These activities will help you continue to heal and will increase your energy level.
- Your abdominal muscles are healing, so lift with caution and do not perform any abdominal exercises until a member of your healthcare team gives you permission to do so.
- Most patients have their first adjustment after eating solid food for one week (see REALIZE Band Adjustments for more detail). The exact timing will depend upon your progress. Remember, the REALIZE Band provides some restriction even when it is empty. If you are losing 1 to 2 pounds a week and feeling satisfied with an appropriate portion of food, you may not need an adjustment at this time.



# The REALIZE™ Band Lifestyle

As you progress from recovery to living life with your REALIZE Band, make sure you understand and actively engage in a lifestyle that will support weight loss. Your relationship with food will change because what, when, and how you eat will change. The REALIZE Band can help you feel full faster and stay full longer, but a gastric band will not eliminate the emotional desire to eat. If you have strategies in place to cope with vulnerable moments and turn to your support network for help, you can manage the emotional desire to eat and improve your health.

REALIZE gastric banding surgery on April 5, 2005



Eat and drink in a new way. This means smaller portions and appropriate food choices.

Eat several small nutritionally balanced meals each day. Your healthcare team will give you advice regarding the large variety of foods that are appropriate to maintain healthy and balanced nutrition.

- ▶ Eat approximately 4 ounces (1/2 cup) of food at each meal. Protein will stay in your upper stomach longer than other foods.
- Do not snack between meals.
- Sip 64 ounces (8 cups) of low-calorie. non-carbonated fluids daily.
- You may want to avoid carbonated beverages because bubbles in these drinks may temporarily block the stoma, may cause discomfort, and may increase burping.

- Do not drink anything 15 to 30 minutes before a meal and do not drink during a meal. Wait 30 to 60 minutes after a meal before drinking anything. Liquid will cause food to empty from your upper stomach too quickly. The goal is to keep food in your upper stomach so that you feel full sooner and stay full longer.
- c Take very small bites. Chew each bite slowly and thoroughly.
- Wait a few moments between each bite.
- Avoid foods that may block your. stoma. Examples include bread, pineapple, celery, fibrous foods, and non-tender cuts of red meats. Later, as you become accustomed to your REALIZE Band, you may find that you do not have to avoid these foods.





# Exercise to reach your goals.

- The REALIZE Band is an investment in your life. It will work with you, but it cannot do all the work for you.
- Do 20 to 30 minutes of aerobic exercise three to four times each week. Examples include walking, jogging, cycling, and swimming.
- Begin weight training when a member of your healthcare team says you are ready. High repetitions of low weights increase metabolism and promote weight loss.
- Enjoy a full range of physical activities. The REALIZE Band does not limit your ability to participate in sports or other physical activities.



## Listen to your REALIZE Band and pay attention to the signals it sends to your body.

- Regurgitation, nausea, acid reflux, constipation, and diarrhea may be signs that you need to eat less, eat more slowly, chew thoroughly, or eat different foods.
- Intolerance to some foods may develop. This is common, but the specific food intolerance is different for each individual.
- Dehydration is a sign that you need to drink more fluids.
- Pressure at the top of your stomach or hiccups are examples of signs that your upper stomach is full. If you continue to eat past these signals, you may experience discomfort.
- Abdominal pain that lasts more than three hours means that you need to contact your surgeon right away.
- With time, you will learn how to interpret these signals and how to eat and drink to prevent discomfort.

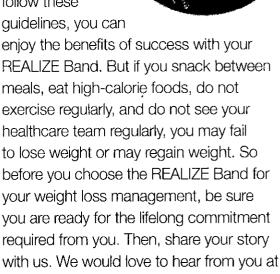
- Seven follow-up visits with healthcare team\*
- Four follow-up visits with healthcare team\*
- Three follow-up visits with healthcare team\*



## See your healthcare team on a regular basis for adjustments and follow-up care.

- Continue your relationship with your healthcare team as long as you have your REALIZE Band.
- Have periodic band adjustments. Your weight will be monitored to determine when adjustments are necessary. Even after you have reached your weight loss goal, maintenance adjustments still may be required. Patients in the U.S. clinical study needed an average of four adjustments during their first year, two during their second year, and two during their third year after surgery.
- Participate in virtual or live support groups. These relationships provide support and motivation.
- Keep a journal of the things you eat and record your reactions to different types of foods. This information will help you and your healthcare team evaluate your progress.

Ultimately, you are responsible for your transformation to better health. If you follow these



www.RealizeBand.com.

## **Treatment Alternatives**

There are nonsurgical alternatives to gastric banding surgery, including supervised diets, exercise programs, behavior modification programs, and prescription drugs.

The two most common surgical alternatives to gastric banding surgery include the Roux-en-Y Gastric Bypass and the Biliopancreatic Diversion with Duodenal Switch (BPD/DS). You may have heard these surgeries referred to as "stomach stapling." These alternative surgeries use different methods to reduce stomach size and shorten the intestines. Because the intestines are shortened, the body cannot absorb as many calories or nutrients. This results in weight loss.

If you are interested in learning more about alternative surgical treatments for weight loss, go to www.RealizeBand.com. If you prefer, you can call 1-866-REALIZE (1-866-732-5493) for more information.

## We Are Here for You

Congratulations! You have just completed Success Factor 1: Educate Yourself. Our goal has been to help you determine whether you are ready for the life changes that come with a REALIZE Adjustable Gastric Band. We have shared what we know from more than 10 years of clinical experience outside the U.S., from our U.S. clinical trial, and from what other patients have told us about the gastric banding lifestyle.

We hope this information has been helpful. If you would like to learn more about gastric banding, please visit www.RealizeBand.com. If you want to speak directly with one of our experienced nurses, you can call 1-866-REALIZE (1-866-732-5493).

## Resources

- BMI and ideal weight calculations: www.RealizeBand.com
- 2. Surgeon Locator: www.RealizeBand.com

Note: Always follow your surgeon's directions. The information provided in this book applies to the general population of individuals who may benefit from the REALIZE Band. But your surgeon knows your specific clinical needs and personal goals and, therefore, may give you information that is different from the information provided in this booklet. In that situation, *always* follow your surgeon's directions and your healthcare team's advice.

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# **Journal Pages**

Collect all your questions, concerns, thoughts, and ideas on this page. Then, when you are ready to talk to your healthcare team, you will have your questions ready for discussion. You also can use this page to take notes when you talk with your healthcare team. If you want to talk with someone before you choose a surgeon, or at any time during your journey to health, please call 1-866-REALIZE (1-866-732-5493).



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